



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/597,714

04/27/2007

Anders Carlsson

D7873.0003

5273

32172 7590 03/16/2010  
DICKSTEIN SHAPIRO LLP  
1633 Broadway  
NEW YORK, NY 10019

EXAMINER

MILLIGAN, ADAM C

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

03/16/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## DETAILED ACTION

Applicants arguments, filed 12/4/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1-7, 9-12, 14, 15, and 17-19** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Herslof (WO 03/068267 – see PTO-892 dated 4/22/09) in view of Tomaru et al. (Colonic Giant Migrating Contractions Induced by Glycerol Enema in Anesthetized Rats - Japan. J. Pharmacol. Vol. 63, Pages 525 -528, 1993) and Klaschik et al (Constipation, Modern laxative therapy Support Care Cancer Vol. 11, Pages 679–685, 2003).

Applicants assert that Klaschik discloses a rectally-administered tablet, while the amended claims are now drawn to an injectable formulation. Also, while Klaschik mentions enemas, it further teaches the administration of enemas is problematic because of leakage, and the instant invention does not suffer from this drawback. Lastly, Applicants argue that adjusting the amount of water for a use as described in Klaschik is not valid since Klaschik's use involves administering a tablet.

Examiner disagrees. In addition to tablets, Klaschik teaches that rectal laxatives may include enemas and clysmas (Klaschik at p.683, rectal laxatives). Clysmas contain a combination of secretagogue-acting agents or stool softeners for rectal application (id). Enemas are the application of larger amounts of fluid into the rectum (id). The effect of the enema depends upon the amount of fluid applied (id).

It would have been obvious to one of ordinary skill in the art to formulate the clyσμα or enema and modify the amount of fluid present to obtain the desired constipation relief. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It is noted that dissolving constipation is only an intended use of the claimed composition. Also, the addition of the phrase “of the composition as a whole”, while providing clarification, does not change the interpretation of “a constipation-dissolving amount”. A “constipation-dissolving amount” is interpreted as any amount given that any amount of the composition would be expected to provide some dissolving effect and the instant claims are directed to a composition & not a method of treating the constipation.

**Claims 21-23** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Herslof (WO 03/068267 – see PTO-892 dated 4/22/09) in view of Klaschik (Constipation, Modern laxative therapy Support Care Cancer Vol. 11, Pages 679–685, 2003), and Stemmler (U.S. 4,828,839).

Applicants argue that Stemmler teaches dynamic viscosity, but only to make the comparison between various batches of tablets to see if they are consistent with one another. Also, Applicants point out that Herslof does not teach that the composition itself has any particular viscosity, but test the composition after first swelling the tablets in water and stirring. Thus, Applicants argue that the dynamic viscosity disclosed is not related to the other prior art.

Examiner disagrees. As discussed above, the combination of Herslof and Klaschik renders a clyisma, or small enema obvious. In formulating the clyisma composition, the constipation-dissolving ingredients, which in Stemmler are taught to be in the form of a tablet, would be mixed with water. Thus, the fact that Stemmler discloses that the dynamic viscosity is related to dissolved ingredients (tablet) in water is consistent with the reasoning of the above rejection, and thus renders the dynamic viscosities recited in claims 21-23 obvious.

Further, since the viscosity of water at 20°C is 1.0020 millipascal seconds<sup>1</sup> ( $1.002 \times 10^{-3}$  Pa·S), the addition of water is reasonably expected to decrease the viscosity of the composition rendered obvious which is taught to have a dynamic viscosity of 0.3 Pa·S to about 1.4 Pa·S. Thus, where the amount of water is adjusted to optimize constipation dissolving, the dynamic viscosity will also vary. In other words, the dynamic viscosity may be adjusted by adjusting the amount of water present for optimal constipation dissolving properties. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

---

<sup>1</sup> The Physics Hypertextbook-Viscosity, <http://physics.info/viscosity/> accessed 3/11/2010.

Art Unit: 1612

ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

### ***Conclusion***

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612

/A. M./  
Examiner, Art Unit 1612